

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

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|-------------------------------|---|---------------------------------|
| JEROME CANADY, M.D. and ARGON | : | |
| ELECTRO-SURGICAL CORP., | : | Civil Action No.: 96-2012 (RMU) |
| | : | |
| Plaintiffs, | : | |
| | : | Document No.: 128 |
| v. | : | |
| | : | |
| ERBE ELEKTROMEDIZIN GmbH and | : | |
| ERBE U.S.A., | : | |
| | : | |
| Defendants. | : | |

MEMORANDUM OPINION

DENYING THE PLAINTIFFS' MOTION TO LIFT THE STAY

I. INTRODUCTION

This matter is before the court on the plaintiffs' motion to lift the stay imposed by this court on July 28, 2000 pending the outcome of reexamination proceedings before the U.S. Patent and Trademark Office ("PTO"). U.S. Patent Number 5,207,675 ("the 675 patent"), the patent at issue in this action, describes an electrosurgical¹ device capable of facilitating blood coagulation² during surgical procedures. The plaintiffs, Jerome Canady and Argon Electro-Surgical Corporation, own the 675 patent. The defendants, Erbe U.S.A. and its German parent corporation, Erbe Elektromedizin GmbH, manufacture and

¹ Electrosurgery refers to the class of surgical procedures "in which electricity is required either in the actual surgical apparatus or in the application of electrical cautery." Taber's Cyclopedic Medical Dictionary at 573 (16th ed. 1989). "Cautery" is "a means of destroying tissue by electricity, freezing, heat, or corrosive chemicals." *Id.* at 308.

² Coagulation is the "process of becoming viscous, jellylike, or solid; *especially* the change from a liquid to a thickened curdlike state not by evaporation but by chemical reaction." Merriam & Webster's Medical Dictionary, available at <http://www.nlm.nih.gov/medlineplus/dictionaries.html> ("Webster's").

sell several models of a similar electrosurgical device known as an argon plasma coagulation (“APC”) probe.

The plaintiffs seek to lift the stay asserting that by filing a total of three requests for reexamination, the defendants are using PTO proceedings for dilatory purposes, and that continuing the stay presents a tactical disadvantage to the plaintiffs. The defendants counter that the filing of multiple requests for reexamination is proper where the submissions in those requests raise a new question of patentability. Although the PTO has already reviewed the first request for reexamination, it has granted two additional requests for reexamination filed by the defendants on September 24, 2001 and October 12, 2001 respectively. The PTO has merged those additional requests and is currently undergoing reexamination proceedings. The defendants correctly indicate that the PTO’s determination is expected to narrow or resolve many issues in this litigation. Consequently, since the PTO has not rendered a final decision regarding the validity of the plaintiffs’ 675 patent, and the plaintiffs have not sufficiently demonstrated that they will suffer a tactical disadvantage as a result of sustaining the stay, the court denies the plaintiffs’ motion to lift the stay as not ripe for adjudication.

II. BACKGROUND

A. Factual Background

This litigation is the result of a chance meeting of the parties at the “Minimally Invasive Surgery Conference” held in Luxemburg in 1992. Am. Compl. ¶¶ 10-13. At that conference, defendant Erbe Elektromedizin GmbH had a booth demonstrating a new device, the APC, to members of the medical field. *Id.* Plaintiff Canady happened upon

this booth and notified defendant Erbe Elektromedizin of his own similar invention that had been filed with the PTO for patent on July 15, 1991. *Id.* Subsequent communications between the parties revealed that plaintiff Canady's patent was filed first in time and the present litigation ensued. *Id.*

Initially, plaintiff Canady claimed patent infringement by the defendants. Compl. ¶ 12. The defendants counterclaimed that there was no infringement and that plaintiff Canady's patent was invalid because prior art showed that the device was "obvious"³ and merely the combination of two previous patents, Manwaring (U.S. Patent No. 5,122,138 (issued June 16, 1992)) and McGreevy (U.S. Patent No. 4,781,175 (issued November 1, 1988)). Defs.' Counterclaim ¶¶ 23-25. As the case progressed, Argon-Electrosurgical Corp. was joined as a plaintiff on July 14, 1997 when it obtained co-ownership of the 675 patent. Order dated July 14, 1997.

On June 21, 2000, the defendants filed a request for reexamination of the 675 patent with the PTO asserting that substantial new questions of patentability of claims 1 and 7-16 of the 675 patent were raised by certain references not considered by the PTO in

³ The plaintiffs and the defendants have both cited the same article in support of their respective positions. Defs.' Opp'n Ex. 3 (citing Dennis *et al.*, Evaluation of Electrofulguration in Control of Bleeding of Experimental Gastric Ulcers, Digestive Diseases and Sciences, Vol. 24, No. 11 at 845-48 (Nov. 1979)) ("Dennis *et al.*"); Pls.' Mot. Ex. I. The defendants falsely assert that this article points toward the development of argon beam coagulation ("ABC"). Defs.' Opp'n Ex. 5 (Requestor's Reply to Patent Owner's Statement dated Jan. 8, 2001). The plaintiffs have correctly interpreted this research, which involves no application of pure argon during surgery (only a 50 percent mixture of carbon dioxide and argon because the researchers believed that a higher concentration of argon would disrupt biochemical processes within the patient), as concluding that the use of argon is inappropriate for endoscopy and, thus, cannot be used in high concentrations during surgery. Pls.' Patent Owner's Statement dated Nov. 7, 2000; Dennis *et al.*

plaintiff Canady's patent application. Defs.' Mot. for Stay at 1; Pls.' Mot. to Lift Stay ("Pls.' Mot.") Ex. D. As a result of this request the court entered a stay on July 28, 2000 pending the outcome of the PTO's reexamination.

The PTO granted the defendants' first request for reexamination on September 12, 2000 finding a "substantial new question of patentability" affecting claims 1 and 7-16 of the 675 patent. Defs.' Opp'n Ex. 2 at 2.⁴ On November 7, 2000, plaintiff Canady filed a patent owner's statement pursuant to the reexamination procedure, opposing the defendants' first request for reexamination and the PTO's decision to grant that request. *Id.* Plaintiff Canady submitted to the PTO a self-declaration under 37 C.F.R. § 1.132 supporting his position that no substantial questions of patentability were raised by the references submitted by the defendants. *Id.* On January 8, 2001, the defendants filed their requestor's reply to plaintiff Canady's patent owner's statement. *Id.* In response to the arguments in the November 7, 2000 patent owner's statement and the requestor's reply, the PTO issued an office action⁵ on June 24, 2001, rejecting plaintiff Canady's claims 1, 2, and 7-16 as unpatentable. *Id.* (citing Ex. 6 (the PTO's office action, dated June 24, 2001)).

Plaintiff Canady then filed a response opposing the PTO's rejection of claims, relying in part on his supplemental declaration under 37 C.F.R. § 1.132. Pls.' Mot. Ex. F. The plaintiffs assert that they did not seek to lift the stay at that time because they

⁴ The plaintiffs do not address the following line of facts regarding the PTO's reexamination proceedings. Therefore, the court relies on information provided in the defendants' opposition to lift the stay and the exhibits attached thereto.

⁵ An office action is a memorandum issued by the PTO describing its decision on a particular matter.

believed the submission of this response would resolve the adverse decision by the PTO, thereby allowing the present litigation to continue. Pls.' Mot. at 2. Since the parties updated the court on the status of this case on August 24, 2001, however, several developments have transpired, both in the PTO's reexamination of the patent and otherwise, which the plaintiffs believe significantly change the circumstances that existed at the time this court entered the stay and which now justify lifting the stay. *Id.*

Specifically, on September 24, 2001, the defendants filed a second request for reexamination, bringing to the PTO's attention two references that were not considered by the PTO either during its initial examination of plaintiff Canady's patent application or during its reexamination pursuant to the defendants' first request. Pls.' Mot. Ex. L. The defendants believe these references (1) refute unsupported and unsupportable factual allegations made in plaintiff Canady's response to the June 24, 2001 office action and in plaintiff Canady's supplemental declaration, and (2) will raise substantial new questions of patentability of the 675 patent when reviewed by the PTO. Defs.' Opp'n at 4. The defendants state that they filed the second request promptly after discovering the two relevant references, assuring that the PTO would have these references available for consideration before issuing another office action in reexamination. *Id.* This task accomplished, the defendants continued to search for additional references to refute plaintiff Canady's arguments and render the 675 patent invalid. *Id.*

The defendants uncovered additional references shortly after they filed their second request. Pls.' Mot. Ex. M. Accordingly, on October 12, 2001, they filed a third request for reexamination, submitting six additional references not considered in any

other PTO proceeding. *Id.* The defendants assert that they did not violate the PTO's reexamination process because they filed their request promptly. Defs.' Opp'n at 15-21.

The PTO granted both the defendants' second and third requests on November 29, 2001 after determining that the references when combined with other submissions in the record "raise a substantial new question of patentability." *Id.* at 6. Plaintiff Canady's opportunity to file a patent owner's statement expired on January 29, 2002. *Id.* Moreover, plaintiff Canady has not challenged the PTO's decision to grant reexamination by filing a petition with the PTO's Director. Defs.' Opp'n at 6; 37 C.F.R. § 1.182. On June 17, 2002, the PTO merged the second and third accepted requests under 37 C.F.R. § 1.565. Defs.' Status Report dated June 17, 2002 (including the PTO's decision to merge, dated June 17, 2002).

1. The PTO's Reexamination

As a result of the high costs of enforcing patent rights, Congress passed the Patent Act of 1980, as amended, 35 U.S.C. §§ 301-07. The purpose of the Patent Act is to allow the reexamination of patent validity in an impartial forum at almost 100 times less cost to the parties by people trained to understand the technologies described in patents. H.R. Rep. No. 1307, 96th Cong., 2d Sess., pt. 7 at 4 (1980) (enacted), *reprinted in* 1980 U.S.C.C.A.N. 6460. In fact, courts often stay proceedings, such as in the instant case, to wait for reexamination results that will simplify litigation by eliminating, clarifying, or limiting the claims. *Ethicon v. Quigg*, 849 F.2d 1422, 1428 (Fed. Cir. 1988).

The Manual of Patent Examining Procedure ("MPEP") outlines the process of reexamination drawing from Title 35 of the United States Code, Title 37 of the Code of Federal Regulations, and the PTO's own practices. Although the Federal Circuit has not

expressly adopted the MPEP, the Federal Circuit generally follows the MPEP. *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 606 (Fed. Cir. 1985) (citing *In re Kaghan*, 387 F.2d 398, 401 (C.C.P.A. 1967) (determining that appellants can rely on procedures outlined by the MPEP)). Reexamination of a patent is initiated when one files a request for reexamination with the PTO regarding the invalidity of any claim in a patent on the basis of prior art. 35 U.S.C. § 302. Prior art consists of patents or printed publications, which are believed to bear on the patentability of any claim in a particular patent. 35 U.S.C. § 301. Where references are submitted to demonstrate that the invention is unpatentable for obviousness (such as in this case), the PTO considers those works as a whole and must demonstrate the desirability and obviousness at the genesis of the invention. 35 U.S.C. § 103; *Hodosh v. Block Drug Co.*, 786 F.2d 1136, 1143 (Fed Cir. 1986). Furthermore, the strength of the references submitted is gauged at the time of the invention, not in hindsight. *Id.*

The PTO grants reexamination when a request demonstrates a “substantial new question of patentability” through patents or prior publications. 35 U.S.C. § 303(a); 37 C.F.R. § 1.515(a); M.P.E.P. § 2240. If the PTO grants reexamination, the PTO will “expidite[] to the extent possible” the reexamination proceedings following receipt of the statement by the patent owner under 37 C.F.R. § 1.530 and the reply by the requestor under 37 C.F.R. § 1.535. M.P.E.P. § 2241. The PTO states that a grant of reexamination need only establish a substantially new question of patentability as to any one of the patent’s claims, even if the request for reexamination does not question that claim. M.P.E.P. § 2242.

Upon a determination by the PTO to grant reexamination, the reexamination itself is conducted *ex parte*. 37 C.F.R. § 1.550(a). The patent owner is given a reasonable period to respond, including any amendments to the patent and new claim(s) the owner may wish to propose. *Id.* If the patent owner files a response and serves it on the requestor, the requestor will then be allowed to reply to that statement within two months. *Id.* After the filing of the patent owner's statement and the requestor's reply, or the time for filing has expired, the reexamination proceeding will continue. 35 U.S.C. § 305; M.P.E.P. § 2254. The patent owner will then have an opportunity to respond to any new rejection before the finalization of the PTO's proceedings in a final office action. 37 C.F.R. § 1.570; M.P.E.P. § 2271.

Where a second or subsequent request for reexamination is filed concurrent with an existing reexamination, as is the case herein, the PTO will determine the presence of a substantial new question of patentability in the second or subsequent request. M.P.E.P. § 2240. If the second request is filed within three months of the first request, the PTO may merge those requests, as was done in this case. 37 C.F.R. § 1.565. The patent owner may petition the PTO to deny the request for reexamination under 37 C.F.R. § 1.182 if the second or subsequent request is filed in an effort to harass or delay pending litigation. M.P.E.P. § 2240. Where the PTO combines the reexamination proceedings, the PTO will issue a single certificate and office action based on the combined proceedings. 37 C.F.R. § 1.565(c).

2. The Inventions at Issue

a. Argon Beam Coagulation

Argon⁶ beam coagulation (“ABC”) can be used in surgery to prevent blood loss and shrink biological tissue through application of a stream of charged argon gas very near to the tissue (about one millimeter from the tissue). Matthews, *Argon Beam Coagulation*, AAORN Journal, Vol. 56, No. 5 at 1 (1992). This technique has been successfully used for the treatment of endometriosis,⁷ removal of liver cysts, and gastrointestinal tract surgery. *Id.*; Kulakov *et al.*, *Argon Beam Coagulator in Laparoscopic Gynecologic Surgery*, Journal of American Associates of Gynecological Laparoscopy, Vol. 3(4) at Supplement 23 (1996) (“Kulakov *et al.*”); Daniell *et al.*, *Laparoscopic Evaluation of the Argon Beam Coagulator*, Journal of Reproductive Medicine, Vol. 30, No. 2 at 121-25 (1993) (“Daniell *et al.*”); Farello *et al.*, *Laparoscopic Cholecystectomy Using Argon Bistoury*, G Chir, Vol. 13(4), at 163-64 (1992)⁸; Lange *et al.*, *Minimally Invasive Interventions in Solitary Liver Cysts*, Chirurg, Vol. 63(4) at 349-52 (1992).⁹ The type of ABC devices in the present litigation do not contact the tissue surface, thus, preventing the eschar¹⁰ from adhering to the electrode, and allowing the

⁶ Argon is a “colorless, odorless, inert (inactive) gas, i.e., it will not react with other elements or molecules in the body. It is one of the safest gases known: it will not support combustion, and it clears the body in one respiratory cycle.” Pls.’ Opp’n to Mot. for Summ. J. at 5.

⁷ Endometriosis is the “presence and growth of functioning endometrial tissue in places other than the uterus that often results in severe pain and infertility.” Webster’s. Endometrial tissue lines the uterine wall.

⁸ This article is printed in an Italian journal.

⁹ This article is printed in a German journal.

¹⁰ An eschar is a “scab formed especially after a burn.” Webster’s.

ABC to be used on delicate tissue. U.S. Patent No. 5,720,745 (issued Feb. 24, 1998) (“the 745 patent”). Further, unlike other comparable devices on the market, the rate of gas discharge and radiofrequency¹¹ (“RF”) current is controllable so that the user can manipulate the device to serve a wide range of functions. *Id.* Publications suggest that this manner of tissue coagulation is exceptionally advantageous to both the patient and the operator. *Supra*, II.A.2.a. In addition to minimizing operation time and cost, ABC devices, such as plaintiff Canady’s as well as others on the market, are safer and increase healing time. Kulakov *et al.*; Daniell *et al.*

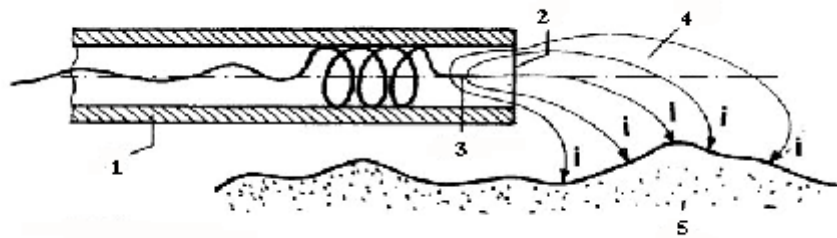


Figure 1

The court adopts Figure 1 from the 745 patent. U.S. Patent No. 5,720,745 (issued Feb. 24, 1998). Figure 1 is a general depiction of a device almost identical to the 675 patent. As designated, the endoscope¹² (1) is a hollow tube that is inserted into the patient at the surgical site. The endoscope houses the tube delivering the argon gas (2). Additionally, a wire (3) capable of delivering the RF current in order to charge the argon

¹¹ The term radiofrequency is defined as “relating to, using, or induced by radio frequencies.” Webster’s. In the situation presented herein, radiofrequency current describes the intensity of the current used to charge the gas.

¹² An endoscope is an “instrument for viewing a hollow organ such as a colon or a lung.” Webster’s.

gas also lies within the endoscope. When argon gas passes through the wire, the gas discharge (4) becomes charged and gains the ability to coagulate blood around the tissue site (5). Both inventions at issue in this case (i.e., the 675 and 745 patents) are functionally similar to this description. *Cf.* U.S. Patent No. 5,207,675 (issued May 4, 1993) to U.S. Patent No. 5,720,745 (issued Feb. 24, 1998).

b. The 675 patent

Plaintiff Canady's 675 patent describes a surgical tissue coagulator that includes a long, biocompatible,¹³ flexible, hollow tube open at both ends. U.S. Patent No. 5,207,675 (issued May 4, 1993). The tube has a diameter (thickness) of five millimeters and can be inserted into an endoscope. *Id.* The proximal¹⁴ end of the tube can be connected with a source of argon gas. *Id.* A handle is attached to the proximal end of the endoscope providing maneuverability to the tube delivering the gas. *Id.* In addition to the tube that delivers the argon gas to the tissue, there is a flexible wire capable of conducting the RF current. *Id.* The wire is capable of discharging an arc of RF energy away from the distal¹⁵ end of the wire into the stream of gas, which will contact the tissue. *Id.*

Plaintiff Canady's patent has 16 claims regarding the characteristics and functions of his tissue coagulator that purport to distinguish his device from others, allegedly making his coagulator patentable. *Id.* These claims are the subject of the defendants'

¹³ Biocompatibility is "the condition of being compatible with living tissue or a living system by not being toxic or injurious and not causing immunological rejection." Webster's.

¹⁴ Proximal means to be "situated next to or near the point of attachment, or origin or a central point." Webster's.

¹⁵ Distal is "situated away from the point of attachment or origin, or a central point." Webster's. With the devices at issue herein (depicted in Figures 2 and 3 *infra*), the distal end is where the device comes in close contact with the tissue.

requests for reexamination to the PTO. To date, the PTO has issued an office action, dated September 12, 2000, stating that claims 1, 2, and 7-16 are not patentable because of prior art.

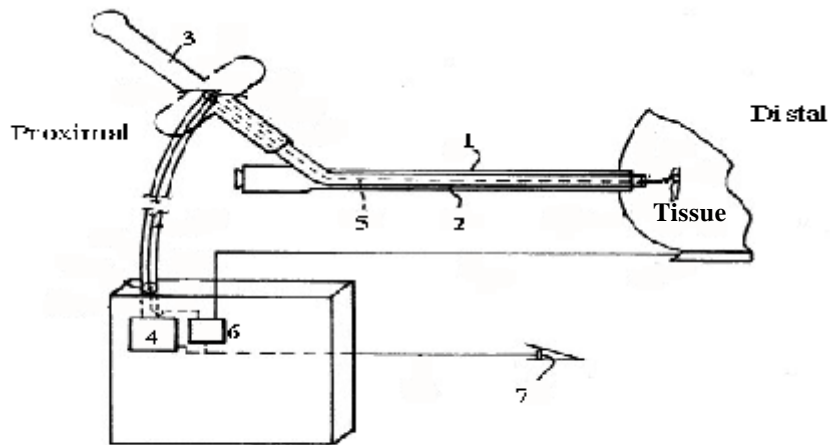


Figure 2

Plaintiff Canady's patent (i.e., the 675 patent) is depicted in Figure 2, and its relevant characteristics in relation to the invention's "preferred embodiment" follow. U.S. Patent No. 5,207,675 (issued May 4, 1993). The proximal and distal ends are noted for reference. *Id.* The present invention can be used with any surgical endoscope (1), which is the hollow tube that houses the invention. *Id.* The tube capable of delivering the argon gas (2) fits within the endoscope and consists of a biocompatible material. *Id.* Plaintiff Canady asserts that his invention is novel because there is a flexible handle (3) located outside of the endoscope, making the inner tube maneuverable. *Id.* The tube within the endoscope capable of delivering argon gas connects with the gas source through tubing located within the handle on the proximal end. *Id.* Connection with the gas source (4) provides for a stream of inert gas to pass through the tube discharging the gas at the tissue site. *Id.* Additionally, a flexible wire (5) inserts within the endoscope

for the purpose of conducting the RF current. *Id.* This wire can be connected to a power source (6) capable of delivering the RF current through the handle of the endoscope. *Id.* When activated, the current will flow to the distal end of the tube where it will discharge into the stream of inert gas at the tissue site, thereby charging the gas so it can coagulate or remove tissue depending on the medical procedure at hand. *Id.* Delivery of the ionizable gas and the RF current occurs by depressing a single pedal foot switch connected to the base unit. *Id.* The gas can be delivered at a variable rate between one and 12 liters per minute. *Id.* The RF generator is capable of delivering 40 to 150 watts of RF current. *Id.* RF current flow is achieved when the distal tip of the wire comes within about one centimeter of the tissue site while the foot pedal switch is depressed. *Id.* The arcing RF current in the gas jet ionizes the argon gas. *Id.* Because the gas delivery tube and the wire for delivering the RF current are flexible, both can be maneuvered to the exact tissue site. *Id.* Plaintiff Canady's patent goes on to assert that other surgical instruments such as biopsy forceps, a polypectomy snare, or a titanium dissection needle can be used with the endoscope. *Id.*

c. The 745 patent

The plaintiffs allege that the defendants are infringing on the 675 patent by selling similar instruments described under the 745 patent by inventor, Dr. Gunther Farin. Am. Compl. ¶ 14. Notably, the plaintiff does not assert the 675 patent as prior to the 745 patent in the case at bar. The 48 claims in the 745 patent describe an electrosurgical unit and method for achieving coagulation of biological tissue through APC, which is the same function of the 675 patent. Compare U.S. Patent No. 5,720,745 (issued Feb. 24, 1998) to U.S. Patent No. 5,720,675 (issued May 4, 1993). Similarly, the 745 invention

describes a flexible, hollow tube capable of delivering an inert, ionizable gas, but describes the wire that delivers the RF current to the gas as stationary. *Id.* Unlike the 675 patent, the 745 patent does not describe a handle to maneuver the tube within the endoscope. *Id.* The 745 patent is illustrated in Figure 3. *Id.*

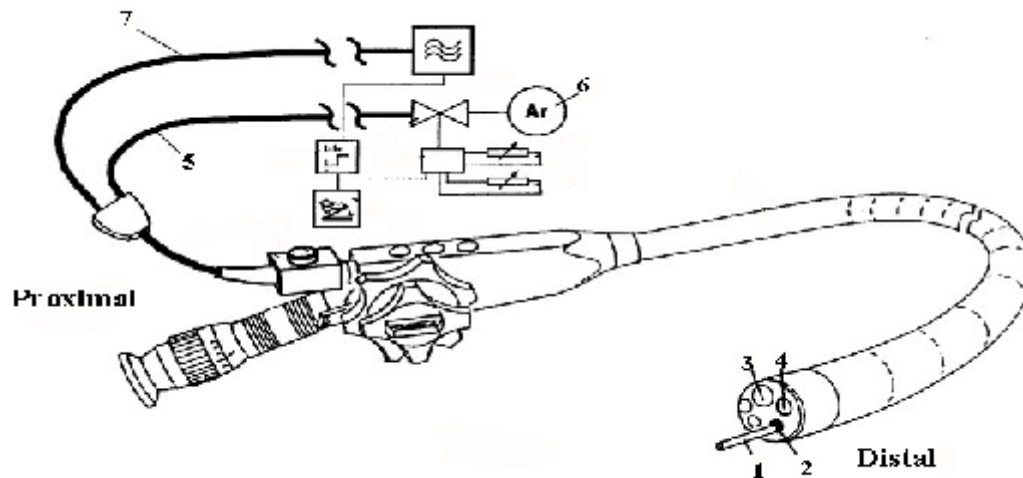


Figure 3

As in Figure 2, the proximal and distal ends of the device are indicated. Like the 675 patent, an endoscope is used as the hollow tube capable of housing the tubes that respectively deliver both the gas and the RF current. *Id.* Tube one (1) protrudes out of the distal end of a working channel (2). *Id.* Channel three (3) allows for viewing optics. *Id.* Additionally, there is a second working channel (4) that can be used for other instrumentation depending on the subject medical procedure. *Id.* Tube one is connected with a gas supply through the conduit (5) located at the proximal end of the device. *Id.* The gas reservoir (6) is also located at the proximal end of the device. *Id.* A wire (7) is connected to a high-frequency voltage source to charge the inert argon. *Id.* Like the 675 patent, the operator can control gas delivery and the current frequency with a pedal. *Id.*

B. Procedural History

Plaintiff Canady initiated the instant action by filing his complaint on August 29, 1996, seeking a declaratory judgment that the defendant's APC probes infringe various claims of the 675 patent. Compl. at 3-4. The defendants filed a counterclaim on August 5, 1997 contending that "prior art" not considered by the PTO in certifying the 675 patent anticipated and rendered obvious the 675 patent. Defs.' Counterclaim at 7-8. On July 14, 1997, plaintiff Canady filed an amended complaint adding Argon Electro-Surgical Corporation as a plaintiff. On February 27, 1998, the defendants moved for summary judgment declaring that (1) the 675 patent is invalid and (2) in any event, their APC probes do not infringe on the plaintiffs' 675 patent. Defs.' Mot. for Summ. J. at 1-4. By Memorandum Opinion and order dated September 10, 1998, this court denied the defendants' motion for summary judgment on patent invalidity but granted their motion for summary judgment on the noninfringement issue.¹⁶ *Canady v. Erbe*, 20 F. Supp. 2d 54 (D.D.C. 1998).

The plaintiffs appealed the court's partial grant of summary judgment to the Federal Circuit.¹⁷ On May 10, 1999, the Federal Circuit affirmed this court's decision without opinion. *Canady v. Erbe*, 194 F.3d 1335 (Fed. Cir. 1999).

On April 28, 1999, the plaintiffs filed a motion with this court for relief from the

¹⁶ The defendants also moved for default judgment, claiming that the plaintiffs failed to answer or otherwise respond to their counterclaims. Because the court granted the defendants' motion for summary judgment on the issue of noninfringement, holding that their APC probes did not infringe upon Canady's 675 patent, the court denied as moot the defendants' motion for default judgment. Mem. Op. and Order dated Sept. 10, 1998.

¹⁷ The defendants gave notice of the appeal, which was filed on October 8, 1998, and did not appeal the portion of the court's ruling denying their motion for summary judgment on patent invalidity.

court's September 10, 1998 ruling.¹⁸ The plaintiffs alleged that the defendants wrongfully withheld documents that could have supplied the plaintiffs with a meritorious response to the defendants' motion for summary judgment of noninfringement. The court granted the plaintiffs relief from summary judgment by its Memorandum Opinion and Order dated March 31, 2000. *Canady v. Erbe*, 99 F. Supp. 2d 37 (D.D.C. 2000). Thus, the issues of infringement and patent validity are still pending before this court.

On July 28, 2000, this court entered a stay of this litigation pending the resolution of the plaintiffs' motion for sanctions due to discovery misconduct and the defendants' request for a reexamination by the PTO. Order dated July 28, 2000. Magistrate Judge Kay resolved the motion for sanctions on December 14, 2000 by issuing an order awarding sanctions to the plaintiffs. Order dated Dec. 14, 2000. The stay has remained in effect pending the reexamination proceedings instituted by the defendants with the PTO.

On January 11, 2002, the plaintiffs filed a motion to lift the stay. The plaintiffs assert that the defendants have delayed the PTO's ruling on the first request for reexamination concerning the validity of the plaintiffs' patent by filing the two additional requests for reexamination on September 24, 2001 and October 12, 2001, and that maintaining the stay presents a tactical disadvantage to the plaintiffs. Pls.' Mot. at 1. The defendants counter that their requests for reexamination are proper and that this court should maintain the stay until the PTO renders its decision. Defs.' Opp'n. at 23-24. At the court's request, the defendants notified the court that on June 17, 2002, the PTO

¹⁸ Stating the obvious, the plaintiffs did not seek relief from the portion of the court's ruling that denied the defendants' motion for summary judgment on patent invalidity.

merged the second and third accepted requests under 37 C.F.R. § 1.565. Defs.’ Status Report dated June 17, 2002 (including the PTO’s voucher, dated June 17, 2002).

III. ANALYSIS

A. Legal Standard for Lifting a Stay

When circumstances have changed such that the court’s reasons for imposing the stay no longer exist or are inappropriate, the court may lift the stay. *Purolite Int’l, Ltd. v. Rohm & Haas Co.*, 24 U.S.P.Q. 2d 1857 (E.D. Pa. 1992); *Rohm & Haas Co. v. Brotech Corp.*, 24 U.S.P.Q. 2d 1369 (D. Del. 1992). A trial court has broad discretion to stay all proceedings in an action pending the resolution of independent proceedings elsewhere. *Landis v. North American Co.*, 299 U.S. 248, 254 (1936). “The power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants.” *Airline Pilots Ass’n v. Miller*, 523 U.S. 866, 879 n.6 (1998) (quoting *Landis*, 299 U.S. at 254-55). Indeed, “[a] trial court may, with propriety, find it is efficient for its own docket and the fairest course for the parties to enter a stay of an action before it, pending resolution of independent proceedings which bear upon the case.” *Levy v. Certified Grocers of California, Ltd.*, 593 F.2d 857, 863-64 (9th Cir. 1979). Logically, the same court that imposes a stay of litigation has the inherent power and discretion to lift the stay. *Purolite Int’l, Ltd.*, 24 U.S.P.Q. 2d at 1857; *Rohm & Haas Co.*, 24 U.S.P.Q. 2d at 1369.

B. Legal Standard for Ripeness

Before a court may consider the merits of a case, the court must determine whether the case is ripe for review so that it has subject-matter jurisdiction. *Tari v. Collier County*, 56 F.3d 1533, 1535-36 (11th Cir. 1995). The Supreme Court has held that Article III's case-or-controversy requirement prohibits courts from issuing advisory opinions or decisions based on hypothetical facts or abstract issues. *Flast v. Cohen*, 392 U.S. 83, 96 (1968).

The ripeness doctrine asks “whether the case has been brought at a point so early that it is not yet clear whether a real dispute to be resolved exists between the parties.” 15 Moore’s Federal Practice 3d § 101.70 [2]. In other words, the ripeness doctrine’s “basic rationale is to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties.” *Abbott Laboratories v. Gardner*, 387 U.S. 136, 148-49 (1967). The Supreme Court has instructed district courts to consider whether a dispute is fit for judicial review and whether withholding court consideration would cause hardship to the parties. *Id.*

A claim involving an administrative agency action is ripe only when the agency action is final. 5 U.S.C. § 704. If the dispute concerns offenses that have not yet occurred, the plaintiff must show that the probability of the future event occurring is of “sufficient immediacy and reality” to provide a concrete set of circumstances on which the court can rule. *Steffel v. Thompson*, 415 U.S. 452, 460 (1974).

C. The Court Denies the Plaintiffs' Motion to Lift the Stay

To determine whether the plaintiffs' instant motion to lift the stay is ripe, the court must "evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Texas v. United States*, 523 U.S. 296, 300-301 (1998); *Abbott Laboratories*, 387 U.S. at 136. Where an administrative agency's proceedings are ongoing, "depending on the agency's future actions . . . review [of the case] now may turn out to [be] unnecessary" later and could also result in depriving the agency of the opportunity to apply its expertise. *Pfizer, Inc. v. Dep't of Health and Human Servs.*, 182 F.3d 975, 978 (D.C. Cir. 1999) (denying a motion for review of a pending petition filed with an agency because it was not ripe) (quoting *Ohio Forestry Ass'n v. Sierra Club*, 523 U.S. 726 (1998) (finding that the controversy was not ripe for review because judicial intervention would inappropriately interfere with further administrative action)). As with the case at bar, where issues require technical expertise and that expertise is available through an administrative agency, the court should allow that agency to come to a final determination before rendering a decision on that issue. *Id.* As noted earlier, the court may abandon its imposed stay of litigation if the circumstances that persuaded the court to impose the stay in the first place have changed significantly. *Purolite Int'l*, 24 U.S.P.Q. 2d at 1857; *Rohm & Haas Co.*, 24 U.S.P.Q. 2d at 1369.

1. The Controversy Is Not Ripe for Adjudication¹⁹

In *R&D Laboratories, Inc. v. Food and Drug Admin.*, 2000 U.S. Dist. LEXIS 20209 (D.D.C. 2000) (Green, J.), the FDA accepted a new drug application (“NDA”) from a third-party company when the FDA had already approved the plaintiff’s drug. In approving that drug, the FDA granted the plaintiff exclusivity pursuant to 21 U.S.C. § 505. *Id.* The plaintiff felt that the acceptance of the NDA violated its exclusivity rights. *Id.* The court determined that the mere acceptance of an application was not a final decision and that the FDA was still considering the application, thus concluding that the plaintiff’s claim was not ripe for review. *Id.* The court acknowledged the need to protect agencies from judicial interference and noted its unwillingness to interfere with threshold administrative decisions before their maturation. *Id.*; *Ohio Forestry Ass’n*, 523 U.S. at 732-33.

Applying the reasoning in *R&D Laboratories* to the case at bar, the plaintiffs ask this court to lift the stay, which the court imposed so it could consider the PTO’s decision

¹⁹ As an initial matter, the defendants rightly assert that the plaintiffs have violated Local Civil Rule 7.1(m) by not conferring with the defendants before filing the instant motion to lift the stay. Defs.’ Opp’n at 1 n.1; LCvR 7.1(m). Local Civil Rule 7.1(m) requires a meet and confer session regardless of whether or not counsel believes it will be productive. *Niedermeier v. Office of Max S. Baucus*, 153 F. Supp. 2d 23, 27 (D.D.C. 2001) (Hogan, C.J.). The purpose of this rule is “for litigants to attempt to resolve, or . . . narrow, the disputed issues to prevent unnecessary waste of time and effort on any given motion,” not “to simply determine whether the motion will be opposed.” *Alexander v. FBI*, 186 F.R.D. 185, 187 (D.D.C. 1999) (Lamberth, J.). Previously, courts have ordered parties to refile their motions for violating the meet and confer rule. *Id.* at 187-88. However, the plaintiffs’ violation of Rule 7.1(m) will not affect the resolution of the pending motion. *Niedermeier*, 153 F. Supp. 2d at 27; *Gray v. Poole*, 2000 U.S. Dist. LEXIS 20350 *6-7 (D.D.C. 2000) (Oberdorfer, J.) *rev’d in part on other grounds*, 275 F.3d 1113 (2002) (citing *Asia N. America Eastbound Rate Agreement v. BJI Ind., Inc.*, 900 F. Supp 507, 510 (D.D.C. 1995) (Harris, J.)). In the present case, because the plaintiffs have failed to comply with Local Civil Rule 7.1(m) in conjunction with asserting a motion that is not ripe, the court awards the defendants their attorney’s fees and costs incurred while formulating their response to the plaintiffs’ instant motion.

regarding the reexamination of the 675 invention. Pls.' Mot. at 1. Currently, the PTO has rendered an office action stating that claims 1, 2, and 7-11 of the 675 patent are not patentable. Defs.' Opp'n Ex. 6. The plaintiffs have not filed an appeal to the Patent Board of Appeals and Interferences regarding this decision. Defs.' Opp'n at 23. Additionally, as evidenced by information provided by the defendants, the PTO has accepted and combined the defendants' two additional requests for reexamination, and is currently in the process of reviewing the 675 patent in light of these new submissions. Defs.' Status Report dated June 17, 2002. Therefore, quite simply, the court recognizes that the PTO is still considering the patentability of the 675 invention and is conducting reexamination proceedings. Defs.' Opp'n at 5-6. Much like the situation in *R&D Laboratories*, because the PTO has not rendered its final decision, the issues are not ripe for consideration by the court and the court denies the plaintiffs' motion to lift the stay.

2. There Are No New Circumstances That Impose Hardship on the Plaintiffs or Change the Court's Earlier Disposition Imposing the Stay

In order for the court not to defer to agency policy consistent with the institutional and judicial interests favoring a stay of litigation, the plaintiffs must demonstrate hardship or that the agency's action immediately impacts the plaintiffs' daily affairs. *Mollins PLC v. Quigg*, 837 F.2d 1064 (Fed. Cir. 1988) (quoting *Gardner v. Toilet Goods Assoc.*, 384 U.S. 167 (1967)). To that end, the plaintiffs assert that the defendants' intent in filing their additional requests for reexamination was to delay this court's proceedings

and impute a tactical disadvantage to the plaintiffs.²⁰ Pls.' Mot. at 9. Additionally, the plaintiffs claim that the defendants are utilizing the reexamination process to evade evidentiary effects of its prior admissions. Pls.' Mot. at 11.

The defendants made their sequential filings with the PTO for reexamination in a timely manner. As outlined earlier, where litigation is stayed pending a decision by the PTO, reexamination proceedings will be expedited to the extent possible. 37 C.F.R. § 1.535. The first request was filed with the PTO in June 2000 and the court ordered the stay of litigation pending the outcome of that reexamination in July 2001. Order dated July 28, 2001. Indeed, the office action from the PTO indicates that certain claims of the 675 patent are invalid. Defs.' Opp'n at Ex. 6. That fall, the defendants filed two additional requests within three weeks of each other. Given the fact that the defendants' first request was valid, as demonstrated by the PTO's office action, the defendants' position that their subsequent requests were not filed for a dilatory purpose seems reasonable. With respect to the plaintiffs' allegation regarding the defendants' evasion of evidentiary effects, upon closer examination of the record, the court notes that the PTO

²⁰ The plaintiffs argue that they will suffer hardship if the stay is maintained because the defendants will be able to obtain discovery from the plaintiffs through a subpoena in preparation for a separate case pending in another court. Pls.' Mot. at 10. The argument that discovery is halted by maintaining the stay only states the obvious. To wit, the halting of discovery is a natural result to any stay. Additionally, and more importantly, the court notes that discovery in this case closed in 1998. By the plaintiffs asserting this argument, the court can only speculate that the plaintiffs presuppose that this court will grant an expected future motion brought by the plaintiffs to allow further discovery. The court is not prepared to reopen discovery at this juncture. Accordingly, the plaintiffs' argument does not persuade the court to lift the stay.

corrected its initial claims.²¹ Defs.' Opp'n at 24.

In the alternative, the plaintiffs cite a number of cases demonstrating instances in which courts have lifted stays regardless of ongoing proceedings at the PTO. Pls.' Mot. at 2 (citing *Purolite Int'l*, 24 U.S.P.Q. 2d at 1857; *Rohm & Haas Co.*, 24 U.S.P.Q. 2d at 1369; *Sulzer v. Black Clawson Co.*, 1995 WL 363440 (S.D.N.Y. 1995); *Ingro v. Tyco Indus., Inc.*, 227 U.S.P.Q. 69 (N.D. Ill. 1985)). Although none of these decisions are binding on this court, each can be distinguished from the instant case.

For example, in *Purolite*, a stay was lifted notwithstanding a pending reexamination by the PTO because the parties revealed to the court that they would proceed with litigation, no matter the outcome from the PTO. *Purolite Int'l*, 24 U.S.P.Q. 2d 1857 at 3-5. The parties herein have made no such assertion. *But see id.* Likewise, in *Brotech*, the court lifted the stay although reexamination was still proceeding because the PTO indicated that its determination would not invalidate all claims of the patent. *Brotech*, 24 U.S.P.Q. 2d 1369. There has been no such disclosure in this case. *But see id.* Similarly, both the *Ingro* and *Sulzer* courts hinged on lifting a stay when the subject stay was abused or because the reexaminations were not pursued expeditiously. *Ingro*, 227 U.S.P.Q. 69 at 6; *Sulzer* 1995 WL 363440, at *2, 3. There is no evidence to suggest that the defendants herein have not pursued their requests for reexamination expeditiously. *But see id.* To the contrary, the defendants' second and third requests

²¹ The defendants also argue that the plaintiffs' argument to lift the stay is actually a motion opposing the defendants' previous motion to impose the stay. Defs.' Opp'n at 7-8. As the procedural history indicates, the court imposed the stay *sua sponte* and denied the defendants' subsequent motion to impose the stay as moot. Order dated Jan. 5, 2001 at 1. Therefore, the plaintiffs' present motion is not a response to the defendants' prior motion, but an altogether new and separate motion. Accordingly, the court does not deny the plaintiffs' instant motion on the basis of untimeliness.

were filed within one month of each other. Simply put, the abandonment of the stay in this case merely depends on the outcome of the reexamination proceedings currently in progress at the PTO.

In sum, the court declines to disturb the PTO's reexamination proceedings that are presently underway. As indicated by the MPEP, the PTO's determination should be forthcoming in a matter of months. M.P.E.P § 2241. As such, there is good reason to prevent the plaintiffs from pressing their cause concurrently with the PTO's pending review. *Clifton Power Corp. v. FERC*, 2002 U.S. App. LEXIS 12839, at *4, 9 (D.C. Cir. 2002) (citing *TeleSTAR, Inc. v. Fed. Communications Comm'n*, 888 F.2d 132, 134 (D.C. Cir. 1989) (stating that "it is a pointless waste of judicial energy for the court to process any petition for review before the agency has acted on the request" before it)). In addition, there is no evidence to suggest that the defendants have inappropriately delayed the PTO's proceedings and, given the technically specialized issues at bar, the PTO is well equipped to determine the patentability of the 675 invention. *Ohio Forestry Ass'n*, 523 U.S. at 726; *Pfizer*, 182 F.3d at 975. Accordingly, the court denies the plaintiffs' motion as incurably premature at this time.

D. Guiding Standard of Review for an Appeal of the PTO's Decision to This Court

One final point merits attention. Where the PTO has made findings of fact, the Supreme Court has held that it is proper for the Federal Circuit to apply the "arbitrary, capricious, an abuse of discretion," or the "substantial evidence" standard of review set

forth in the Administrative Procedure Act, as amended, 5 U.S.C. § 701 *et seq.*²²

Dickinson, 527 U.S. at 165; *see also Novamedix Dist. Ltd. v. Dickinson*, 175 F. Supp. 2d 8, 9 (D.D.C. 2001) (Roberston, J.). The standard of review applied by the court in

reviewing a decision by the PTO must take into account the serious nature brought by the possibility of displacing the action of an executive department of government.²³

Dickinson, 527 U.S. at 159 (citing *Morgan v. Daniels*, 153 U.S. 120, 124 (1894)).

The court stayed this action pending the PTO's reexamination of the 675 patent's validity.

Congress instituted the reexamination process to shift the burden of reexamination of

patent validity from the courts to the PTO. H.R. Rep. No. 1307, 96th Cong., 2d Sess., pt.

7 at 4 (1980), *reprinted in* 1980 U.S.C.C.A.N. 6460. Patent validity is a commonly

²² The plaintiffs incorrectly assert that a decision by the PTO and the Board of Patent Appeals and Interferences would be reviewable *de novo* by either this court or the Federal Circuit. Pls.' Mot. at 13 (citing *Heinl v. Godici*, 143 F. Supp. 2d 593, 598 (E.D. Va. 2001)). As the *Heinl* court properly stated: "judicial review may then be appropriately sought in either the Federal Circuit based on the administrative record or the District Court for the District of Columbia in a trial *de novo*." *Heinl*, 143 F. Supp. 2d at 598. *Heinl* makes this conclusion, however, in dictum by interpreting 35 U.S.C. § 306, which states, in pertinent part, that a "patent owner . . . may appeal under the provisions of section 134 of this title, and may seek court review under the provisions of sections 141 to 145 of this title, with respect to any decision adverse to the patentability . . ." 35 U.S.C. § 306. Interestingly, none of the aforementioned sections indicate that proceedings will be conducted *de novo*. 35 U.S.C. §§ 134, 141-45. In fact, patent statutes do not use any language to indicate the proper standard of review. *Dickinson v. Zurko*, 527 U.S. 150, 157-58 (1999) (citing 35 U.S.C. §§ 61-62). As such, the plaintiffs are operating under a false assumption with respect to the standard of review of the PTO's decisions.

²³ In preparation for the Supreme Court's decision in *Dickinson*, the Court reviewed 89 pre-APA opinions regarding the proper standard of review. *Dickinson*, 527 U.S. at 155. In nearly half of these cases, the "manifest error" standard was applied, in an effort to recognize the PTO as an expert body, equipped to analyze technically complex subject matter, and is consequently deserving of deference. *Id.* at 160-61 (citations omitted). Statistically, reference to the PTO's advantage of technical understanding has increased by 17 percent from 1936 to 1946 in the opinions examined. *Id.* at 161. With the rapid advancement of technologies, especially in the field of computers and medicine, courts rely even more heavily on the technical expertise of PTO examiners and, thus, the PTO's decisions.

asserted defense in litigation and courts are cognizant of Congress's intention of utilizing the PTO's specialized expertise to reduce costly and timely litigation. *Id.*

The party that receives an adverse decision from the PTO's pending reexamination is not without redress. That party may appeal to the Board of Patent Appeals and Interferences. 35 U.S.C. § 134. When administrative remedies have been exhausted, that party may appeal to either this court or to the Federal Circuit. 35 U.S.C. § 306. Notwithstanding the presentation of new evidence and contrary to the plaintiffs' beliefs, the PTO's decision will not be reviewed *de novo*. *Gould v. Quigg*, 822 F.2d 1074, 1077 (Fed. Cir. 1987). The Supreme Court has recognized that where a district judge is only reviewing the PTO's factfinding, the Federal Circuit may adjust related review standards when necessary. *Dickinson*, 527 U.S. at 165; *see Fregeau v. Mossinghoff*, 776 F.2d 1034, 1038 (Fed. Cir. 1985). This court accords due deference to the PTO's decision regarding the validity of the 675 patent in any potential future appeal. The rationale is the same as stated in *Dickinson*, the PTO is a technically specialized administrative agency well-equipped to examine and determine patentability, and the court will give deference to its decisions. *Dickinson*, 527 U.S. at 165.

IV. CONCLUSION

For the foregoing reasons, the court denies the plaintiffs' motion to lift the stay. Consequently, the court directs the plaintiffs to pay the attorney's fees, costs, and legal expenses relevant to the defendants' opposition to the plaintiffs' motion to lift the stay. An order directing the parties in a manner consistent with this Memorandum Opinion is separately and contemporaneously issued this _____ day of July 2002.

Ricardo M. Urbina
United States District Judge

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

JEROME CANADY *et al.*,

Plaintiffs,

v.

ERBE ELEKTROMEDIZIN GmbH *et al.*,

Defendants.

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Civil Action No.: 1996-2012
(RMU)

Document No.: 128

ORDER

DENYING THE PLAINTIFFS' MOTION TO LIFT THE STAY

For the reasons stated in the court's Memorandum Opinion separately and contemporaneously issued this _____ day of July 2002, it is hereby

ORDERED that the plaintiffs' motion to lift the stay is **DENIED**; and it is

FURTHER ORDERED that the plaintiffs pay the defendants' attorneys' fees, costs, and legal expenses relevant to the defendants' opposition brief filed on January 22, 2002 in response to the plaintiffs' motion to lift the stay; and it is

ORDERED that the defendants have 30 days from the date indicated above to file their list of itemized expenses in preparing the aforementioned opposition brief so that the court can calculate the exact amount which the plaintiffs must pay the defendants; and it is

FURTHER ORDERED that the plaintiffs' counsel are allowed to file a response to the defendants' itemized expenses due within five days from the filing date of the defendants' submission.²⁴

²⁴ The court does not order the plaintiffs to file a response. If the plaintiffs do wish to file a response, however, that response shall be limited to the narrow issue of calculating the proper compensatory sum owed to the defendants. In other words, this is not an opportunity to relitigate the issues resolved by the court in the corresponding Memorandum Opinion.

The court will issue an order listing the exact amount owed to the defendants by the plaintiffs once the court receives the aforementioned submission(s).

SO ORDERED.

Ricardo M. Urbina
United States District Judge

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